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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/573,583 | 08/31/2006 | Stefan Golz | 004974.01113 | 6824 |

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| EXAMINER | |
|---|---|
| MOHAMED, ABDEL A | |

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| 1654 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/573,583 | GOLZ ET AL. | |
| | Examiner | Art Unit | |
| | ABDEL A. MOHAMED | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-47* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**ACKNOWLEDGMENT TO THE PRELIMINARY AMENDMENT AND THE STATUS OF THE CLAIMS**

The preliminary amendment filed 03/27/06 is acknowledged, entered and considered. In view of Applicant's request claims 1-26 have been canceled and claims 27-47 have been added. Claims 27-47 are active and pending in the application.

**ELECTION/RESTRICTION**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 27, 30-37, 45 and 47, drawn to a method of screening for therapeutic agents by contacting a test compound with a RNPEP-like polypeptide, and detecting binding of said test compound to said RNPEP-like polypeptide and to a pharmaceutical composition thereof as recited in claims 45 and 47.

Group II, claims(s) 28, 29, 45 and 47, drawn to a method of screening for therapeutic agents by determining the activity of a RNPEP-like polypeptide at a certain concentration of a test compound or in the absence of said test compound, and determining the activity of said polypeptide at a different concentration of said test compound and to a composition thereof as recited in claims 45 and 47.

Group III, claims 38-43 and 46, drawn to a method of screening for therapeutic agents by contacting a test compound with a RNPEP-like polynucleotide, and detecting binding of said test compound to said RNPEP-like polynucleotide and to a pharmaceutical composition thereof as recited in claim 46.

Group IV, claims 44 and 46, drawn to a method of diagnosing a disease by determining the amount of a RNPEP-like polynucleotide in a sample taken from said mammal, and determining the amount of RNPEP-like polynucleotide in healthy and/or diseased mammals and to a composition thereof as recited in claim 46.

The inventions listed as Groups I-I and III-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The RNPEP-like polypeptide of Groups I-II are related to the RNPEP-like polynucleotide of Groups III-IV by virtue of encoding same, but are distinctly different products with different biological, physical and chemical structures and functions. Although, the compositions of Groups I-II as recited in claim 45 have various therapeutic agents, for example, including a polypeptide and antibody while the compositions of Groups III-IV as recited in claim 46 comprises RNPEP-like polynucleotide. The Composition of polynucleotide of Groups III-IV and the antibody recited in the composition of Groups I-II in claim 45 are unrelated since the polypeptide is encoded by the nucleic acid and is not the antibody. Also, the polynucleotide itself is not necessary for the antibody production and both are wholly different compounds having different compositions and functions.

In regard to method of Groups I-IV, the methods do not correspond to the same technical features and are not connected in design, operation or effect because they differ in method steps, parameters and reagents used, and as such, the method of Group I is directed to a method of screening for therapeutic agents by contacting a test compound with a RNPEP-like polypeptide, and detecting binding of said test compound to said RNPEP-like polypeptide. Group II is directed to a method of screening for therapeutic agents by determining the activity of a RNPEP-like polypeptide at a certain concentration of a test compound or in the absence of said test compound, and determining the activity of said polypeptide at a different concentration of said test compound. Group III is directed to a method of screening for therapeutic agents by contacting a test compound with a RNPEP-like polynucleotide, and detecting binding of said test compound to said RNPEP-like polynucleotide. Group IV is directed to a method of diagnosing a disease by determining the amount of a RNPEP-like polynucleotide in a sample taken from said mammal, and determining the amount of RNPEP-like polynucleotide in healthy and/or diseased mammals. Therefore, the methods of Groups I-IV as recited above do not correspond to the same technical features and are not connected in design, operations or effects because they differ in method steps, parameters and reagents used and functions, and as such, the methods as grouped are independent and distinct, each from the other because they represent different technical features and different inventive endeavors. Thus, the Groups require different patent and literature search and as such Groups I-IV do not share the same technical features, the inventions do not relate to the same inventive concept.

**ELECTION OF SPECIES**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If either Group I or Group II is elected, further restriction requirement is necessary as recited in claim 45.

The species are as follows:

Species I, a small molecule,

Species II, an RNA molecule,

Species III, an antisense oligonucleotide,

Species IV, a polypeptide,

Species V, an antibody, or

Species VI, a ribozyme.

Whichever groups are elected, the above listed species should be elected along the elected groups. Applicant is required, in reply to this action, to elect a single species along the elected group to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species I-VI are related as independent formulations comprising different active ingredients as shown above.

The following claim(s) are generic: claims 27, 30-34 and 47 if Group I is elected. Claims 28, 29 and 47 are generic if Group II is elected.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Species I-VI do not correspond to the same technical feature and are not connected in design, operation or effect because they differ in structure and formulation, and as such, the therapeutic agents as grouped in Species I-VI are different from each other because they represent different technical features and different inventive endeavors. Hence, the pharmaceutical composition comprising the therapeutic agents disclosed as Species I-VI in claim 45 have different structures, functions and different effects. Thus, the species require different patent and literature search and a reference teaching an agent which is a small molecule (Species I), or an RNA molecule (Species II), or an antisense oligonucleotide (Species III) will not teach an agent which is a polypeptide (Species IV), or an antibody (Species V), or a ribozyme (Species VI) and *vice versa*. Therefore, the

species cited as Species I-VI above do not share the same technical features, the inventions do not relate to a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions and species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions and species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

## CONCLUSION AND FUTURE CORRESPONDANCE

Claims 27-47 are subject to restriction and/or species election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657